"METHODS FOR CONTROLLING THE INTERNAL CIRCUMFERENCE OF AN ANATOMIC ORIFICE OR LUMEN"

CROSS-REFERENCE TO RELATED APPLICATIONS

The present application claims priority of U.S. Provisional Application Serial No. 60/406,841 filed August 29, 2002; U.S. Provisional Application Serial No. 60/444,005, filed January 31, 2003; U.S. Provisional Application Serial No. 60/447,383, filed February 14, 2003; and U.S. Provisional Application Serial No. 60/462,435, filed April 12, 2003.

TECHNICAL FIELD

The present invention relates generally to surgical procedures and relates more specifically to surgical procedures for controlling the internal circumference of an anatomic orifice or lumen.

BACKGROUND OF THE INVENTION

Many anatomic structures in the mammalian body are hollow passages in which walls of tissue define a central lumen, which serves as a conduit for blood, other physiologic fluids, nutrient matter, or waste matter passing within the structure. In many physiologic settings, dysfunction may result from a structural lumen which is

either too large or too small. In most such cases, dysfunction can be relieved by interventional changes in the luminal size.

Thus in surgery, there is often a need to reduce the internal circumference of an orifice or other open anatomic structure to narrow the size of the orifice or opening to achieve a desired physiologic effect. Often, such surgical procedures require interruption in the normal physiologic flow of blood, other physiologic fluids, or other structural contents through the orifice or structure. The exact amount of the narrowing required for the desired effect often cannot be fully appreciated until physiologic flow through the orifice or structure is resumed. It would be advantageous, therefore, to have an adjustable means of achieving this narrowing effect, such that the degree of narrowing could be changed after its implantation, but after the resumption of normal flow *in situ*.

One example of a dysfunction within an anatomic lumen is in the area of cardiac surgery, and specifically valvular repair. Approximately one million open heart surgical procedures are now performed annually in the United States, and twenty percent of these operations are related to cardiac valves.

The field of cardiac surgery was previously transformed by the introduction of the pump oxygenator, which allowed open heart surgery to be performed. Valvular heart surgery was made possible by the further introduction of the mechanical ball-valve prosthesis, and many modifications and different forms of prosthetic heart valves have since been developed. However, the ideal prosthetic valve has yet to be designed, which attests to the elegant form and function of the native heart valve. As a result of the difficulties in engineering a perfect prosthetic heart valve, there has been growing interest in repairing a patient's native valve. These efforts have documented equal long-term durability to the use of mechanical prostheses, with added benefits of better ventricular performance due to preservation of the subvalvular mechanisms and obviation of the need for chronic anticoagulation. Mitral valve repair has become one of the most rapidly growing areas in adult cardiac surgery today.

Mitral valve disease can be subdivided into intrinsic valve disturbances and pathology extrinsic to the mitral valve ultimately affecting valvular function. Although these subdivisions exist, many of the repair techniques and overall operative approaches are similar in the various pathologies that exist.

Historically, most valvular pathology was secondary to rheumatic heart disease, a result of a streptococcal infection, most commonly affecting the mitral valve, followed by the aortic valve, and least often the pulmonic valve. The results of the infectious process are mitral stenosis and aortic stenosis, followed by mitral insufficiency and aortic insufficiency. With the advent of better antibiotic therapies, the incidence of rheumatic heart disease is on the decline, and accounts for a smaller percentage of valvular heart conditions in the developed world of the present day. Commissurotomy of rheumatic mitral stenosis was an early example of commonly practiced mitral valve repair outside of the realm of congenital heart defects. However, the repairs of rheumatic insufficient valves have not met with good results due to the underlying valve pathology and the progression of disease.

Most mitral valve disease other than rheumatic results in valvular insufficiency that is generally amenable to repair. Chordae rupture is a common cause of mitral insufficiency, resulting in a focal area of regurgitation. Classically, one of the first successful and accepted surgical repairs was for ruptured chordae of the posterior mitral leaflet. The technical feasibility of this repair, its reproducible good results, and its long-term durability led the pioneer surgeons in the field of mitral valve repair to attempt repairs of other valve pathologies.

Mitral valve prolapse is a fairly common condition that leads over time to valvular insufficiency. In this disease, the plane of coaptation of the anterior and posterior leaflets is "atrialized" relative to a normal valve. This problem may readily be repaired by restoring the plane of coaptation into the ventricle.

The papillary muscles within the left ventricle support the mitral valve and aid in its function. Papillary muscle dysfunction,

whether due to infarction or ischemia from coronary artery disease, often leads to mitral insufficiency (commonly referred to as ischemic mitral insufficiency). Within the scope of mitral valve disease, this is the most rapidly growing area for valve repair. Historically, only patients with severe mitral insufficiency were repaired or replaced, but there is increasing support in the surgical literature to support valve repair in patients with moderate insufficiency that is attributable to ischemic mitral insufficiency. Early aggressive valve repair in this patient population has been shown to increase survival and improve long-term ventricular function.

In addition, in patients with dilated cardiomyopathy the etiology of mitral insufficiency is the lack of coaptation of the valve leaflets from a dilated ventricle. The resultant regurgitation is due to the lack of coaptation of the leaflets. There is a growing trend to repair these valves, thereby repairing the insufficiency and restoring ventricular geometry, thus improving overall ventricular function.

The two essential features of mitral valve repair are to fix primary valvular pathology (if present) and to support the annulus or reduce the annular dimension using a prosthesis that is commonly in the form of a ring or band. The problem encountered in mitral valve repair is the surgeon's inability to fully assess the effectiveness of the repair until the heart has been fully closed, and the patient is weaned off cardiopulmonary bypass. Once this has been achieved, valvular function can be assessed in the operating room using transesophageal echocardiography (TEE). If significant residual valvular insufficiency is then documented, the surgeon must re-arrest the heart, re-open the heart, and then re-repair or replace the valve. This increases overall operative, anesthesia, and bypass times, and therefore increases the overall operative risks.

If the prosthesis used to reduce the annulus is larger than the ideal size, mitral insufficiency may persist. If the prosthesis is too small, mitral stenosis may result. The need exists, therefore, for an adjustable prosthesis that would allow a surgeon to adjust the annular dimension *in situ* in a beating heart under TEE guidance or other

diagnostic modalities to achieve optimal valvular sufficiency and function.

Cardiac surgery is but one example of a setting in which adjustment of the annular dimension of an anatomic orifice *in situ* would be desirable. Another example is in the field of gastrointestinal surgery, where the Nissen fundoplication procedure has long been used to narrow the gastro-esophageal junction for relief of gastric reflux into the esophagus. In this setting, a surgeon is conventionally faced with the tension between creating sufficient narrowing to achieve reflux control, but avoiding excessive narrowing that may interfere with the passage of nutrient contents from the esophagus into the stomach. Again, it would be desirable to have a method and apparatus by which the extent to which the gastro-esophageal junction is narrowed could be adjusted *in situ* to achieve optimal balance between these two competing interests.

Aside from the problem of adjusting the internal circumference of body passages *in situ*, there is often a need in medicine and surgery to place a prosthetic implant at a desired recipient anatomic site. For example, existing methods proposed for percutaneous mitral repair include approaches through either the coronary sinus or percutaneous attempts to affix the anterior mitral leaflet to the posterior mitral leaflet. Significant clinical and logistical problems attend both of these existing technologies. In the case of the coronary sinus procedures, percutaneous access to the coronary sinus is technically difficult and time consuming to achieve, with procedures which may require several hours to properly access the coronary sinus. Moreover, these procedures employ incomplete annular rings, which compromise their physiologic effect. Such procedures are typically not effective for improving mitral regurgitation by more than one clinical grade. Finally, coronary sinus procedures carry the potentially disastrous risks of either fatal tears or catastrophic thrombosis of the coronary sinus.

Similarly, percutaneous procedures which employ sutures, clips, or other devices to affix the anterior mitral leaflets to the posterior mitral leaflets also have limited reparative capabilities. Such

procedures are also typically ineffective in providing a complete repair of mitral regurgitation.. Furthermore, surgical experience indicates that such methods are not durable, with likely separation of the affixed valve leaflets. These procedures also fail to address the pathophysiololgy of the dilated mitral annulus in ischemic heart disease. As a result of the residual anatomic pathology, no ventricular remodeling or improved ventricular function is likely with these procedures.

The need exists, therefore, for a delivery system and methods for its use that would avoid the need for open surgery in such exemplary circumstances, and allow delivery, placement, and adjustment of a prosthetic implant to reduce the diameter of such a mitral annulus in a percutaneous or other minimally invasive procedure, while still achieving clinical and physiologic results that are at least the equivalent of the yields of the best open surgical procedures for these same problems.

The preceding cardiac applications are only examples of some applications according to the present invention. Another exemplary application anticipated by the present invention is in the field of gastrointestinal surgery, where the aforementioned Nissen fundoplication procedure has long been used to narrow the gastro-esophageal junction for relief of gastric reflux into the esophagus. In this setting, a surgeon is conventionally faced with the tension between creating sufficient narrowing to achieve reflux control, but avoiding excessive narrowing that may interfere with the passage of nutrient contents from the esophagus into the stomach. Additionally, "gas bloat" may cause the inability to belch, a common complication of over-narrowing of the GE junction. An adjustable prosthetic implant according to the present invention could allow *in situ* adjustment in such a setting under physiologic assessment after primary surgical closure. Such an adjustable prosthetic implant according to the present invention could be placed endoscopically, percutaneously, or with an endoscope placed within a body cavity or organ, or by trans-abdominal or trans-thoracic approaches. In addition, such an adjustable prosthetic implant according to the

present invention could be coupled with an adjustment means capable of being placed in the subcutaneous or other anatomic tissues within the body, such that remote adjustments could be made to the implant during physiologic function of the implant. This adjustment means can also be contained within the implant and adjusted remotely, *i.e.* remote control adjustment. Such an adjustment means might be capable of removal from the body, or might be retained within the body indefinitely for later adjustment.

The present invention and the methods for its use anticipate many alternate embodiments in other potential applications in the broad fields of medicine and surgery. Among the other potential applications anticipated according to the present invention are adjustable implants for use in the treatment of morbid obesity, urinary incontinence, anastomotic strictures, arterial stenosis, urinary incontinence, cervical incompetence, ductal strictures, and anal incontinence. The preceding discussions are intended to be exemplary embodiments according to the present invention and should not be construed to limit the present invention and the methods for its use in any way.

SUMMARY OF THE INVENTION

In a first aspect, the present invention is directed to a novel prosthetic implant and method for use for adjusting the internal circumference of an anatomic passage that can be adjusted after implantation but after the resumption of normal flow of anatomic fluids *in situ*. In another aspect, the present invention is directed to a novel delivery system and methods for its use for the delivery and placement of a prosthetic implant within an anatomic site. Furthermore, the delivery system and methods according to the present invention are capable of *in situ* adjustment of such a prosthetic implant following its placement.

An adjustable prosthetic implant according to a first aspect of the present invention could allow *in situ* adjustment after initial narrowing of the circumference of an internal anatomic passage under physiologic assessment after primary surgical closure. Such an

adjustable prosthetic implant according to the present invention could be placed through an open surgical incision, or it could be placed endoscopically, either percutaneously or with an endoscope placed within a body cavity or organ. In addition, such an adjustable prosthetic implant according to the present invention could be coupled with an adjustment means capable of being placed in the subcutaneous or other anatomic tissues within the body, such that remote adjustments could be made to the implant during physiologic function of the implant. Such an adjustment means might be capable of removal from the body, or might be retained within the body indefinitely for later adjustment.

The present invention and the methods for its use anticipate many alternate embodiments in other potential applications in the broad fields of medicine and surgery. Among the other potential applications anticipated according to the present invention are adjustable implants for use in the treatment of anal incontinence, urinary incontinence, anastomotic strictures, arterial stenosis, urinary incontinence, cervical incompetence, ductal strictures, morbid obesity, and for tricuspid valvular dysfunction. The preceding discussions are intended to be exemplary embodiments according to the present invention and should not be construed to limit the present invention and the methods for its use in any way.

In another exemplary application according to the present invention, a dysfunctional cardiac valve could be replaced or functionally supplemented to relieve disease without the need for open heart surgery by a delivery system and methods for use that would allow placement of a prosthetic heart valve by a similar percutaneous or other minimally invasive procedure.

Objects, features, and advantages of the present invention will become apparent upon reading the following specification, when taken in conjunction with the drawings and the appended claims.

BRIEF DESCRIPTION OF THE DRAWINGS

FIG. 1 is a front view of a first embodiment of an implant for reducing the circumference of an anatomic orifice.

FIG. 2 is a front view of the implant of FIG. 1 secured to the annulus of a mitral valve, with the implant in an expanded position.

FIG. 3 is a front view of the implant of FIG. 1 secured to the annulus of a mitral valve, with the implant in a contracted position to reduced the size of the heart valve opening.

FIG. 4 is a perspective view of a second embodiment of an implant for reducing the circumference of an anatomic orifice, inserted through an open operative cardiac incision and secured around the mitral valve.

FIG. 5 is a perspective view of the implant of FIG. 4, showing the cardiac incision closed, an adjustment tool extending through the closed incision, and adjustment of the implant possible after the patient has been taken "off pump."

FIG. 6 is a perspective view of a first embodiment of an adjustment means for adjusting the circumference of an implant for reducing the circumference of an anatomic orifice.

FIG. 7 is a right side view of the adjustment means of FIG. 6.

FIG. 8 is a left side view of the adjustment means of FIG. 6.

FIG. 9 is a right side view of a second embodiment of an adjustment means for adjusting the circumference of an implant for reducing the circumference of an anatomic orifice.

FIG. 10 is a perspective view of a first alternate embodiment of an attachment means for the implant of FIG. 1.

FIG. 11 is a perspective view of a second alternate embodiment of an attachment means for the implant of FIG. 1.

FIG. 12 is a perspective view of a third embodiment of an implant for reducing the circumference of an anatomic orifice.

FIG. 13 is a perspective view of one end of the implant of FIG. 12 showing an optional keyed relationship between three coaxial cannulae to prevent relative rotation between the three components.

FIG. 14 is a perspective view of the implant of FIG. 12 showing the outer cannula extended to cover the implant.

FIG. 15 is a perspective view of the implant of FIG. 12 showing the outer cannula retracted to expose the implant.

FIG. 16 is a perspective view of the implant of FIG. 12 showing the middle cannula extended to unfold the implant.

FIGS. 17 and **18** are schematic views illustrating how extension of the middle cannula causes the implant to unfold, where

FIG. 17 shows the implant in the folded position, and

FIG. 18 shows the implant in the unfolded position.

FIG. 19 is a perspective view of the lower end of a touchdown sensor of the implant of FIG. 12, showing the sensor in an uncompressed condition.

FIG. 20 is a perspective view of the lower end of the touchdown sensor of FIG. 19, showing the sensor in a compressed condition.

FIG. 21 is a perspective end view of a fourth embodiment of an implant for reducing the circumference of an anatomic orifice.

FIG. 22 is a side view of the implant of FIG. 21 with the implant opened up to show its full length.

FIG. 23 is a side view of the adjustment mechanism of the implant of FIG. 21.

FIG. 24 is a close-up view of two of the retention barbs of the implant of FIG. 21.

FIG. 25 is a front view of a fifth embodiment of an implant for reducing the circumference of an anatomic orifice, with the implant shown in its expanded configuration.

FIG. 26 is a front view of the implant of **FIG. 25**, with the implant shown in its contracted configuration.

FIG. 27 is an enlarged view of the area indicated by the circle *27* in FIG. 25, with the outer body removed to show interior detail.

FIG. 28 is a schematic view showing the implant of FIG. 12 anatomically positioned at the mitral annulus in a heart with the implant in a fully expanded state.

FIG. 29 is a schematic view showing the implant of FIG. 12 anatomically positioned at the gastroesophageal opening with the implant in a fully expanded state.

FIG. 30 is a schematic view showing the implant of FIG. 29 implanted to reduce the circumference of the gastroesophageal opening.

DETAILED DESCRIPTION OF THE DISCLOSED EMBODIMENT

Referring now to the drawings, in which like numerals indicate like elements throughout the several views, an exemplary implant **10** comprising an implant body **15** is shown in Fig. 1. The implant body may be provided in a shape and size determined by the anatomic needs of an intended native recipient anatomic site within a mammalian patient. Such a native recipient anatomic site may be, by way of illustration and not by way of limitation, a heart valve, the esophagus near the gastro-esophageal junction, the anus, or other anatomic sites within a mammalian body that are creating dysfunction that might be relieved by an implant capable of changing the size and shape of that site and maintaining a desired size and shape after surgery.

The implant **10** of FIG. 1 comprises a circular implant body **15** which is provided with adjustable corrugated sections **20** alternating with intervening grommet-like attachment means **25** having narrowed intermediate neck portions. As can be seen in FIGS. 2 and 3, the implant body **15** may be secured to the annulus of a heart valve **30** by a fixation means such as a suture **35** secured over or through the attachment means **25**. The corrugated sections **20** fold and unfold as the circumference of the implant body **15** shortens or lengthens. Adjustment of the implant **10** *in situ* may decrease the overall size of the heart valve **30**, increasing the coaptation of the valve leaflets **40**, and changing the configuration from that shown in FIG. 2 to that shown in FIG. 3.

An additional exemplary embodiment **100** of the present invention is shown in FIGS. 4 and 5, with an open operative cardiac incision **105** in a heart **110** shown in FIG. 4, and closure of the cardiac incision **105** in FIG. 5. As shown in FIG. 4, the exemplary adjustable implant **100** according to the present invention comprises an implant body **115** with attachment means **120** that allows fixation

to the annulus of a mitral valve **125**. The exemplary adjustable implant **100** is further provided with an adjustment means **130** that is controlled by an attached or coupled adjustment tool **135**. After closure of the myocardial incision **105** in FIG. 5, the adjustment tool **135** remains attached or coupled to the adjustment means **130**, so that the size and shape of the implant **100** may further be affected after physiologic flow through the heart **110** is resumed, but with the chest incision still open. Once the desired shape and function are achieved, the adjustment tool **135** may be disengaged from the adjustment means **130** and withdrawn from the myocardial incision **105**. In various embodiments according to the present invention, the adjustment means **130** may be configured and placed to allow retention by or re-introduction of the adjustment tool **135** for adjustment following closure of the chest incision.

To use the implant **100** of FIGS. 4 and 5, the physician makes the open operative incision **105** in the heart **110**, as shown in FIG. 4, in the conventional manner. The implant **100**, mounted at the forward end of adjustment tool **135**, is then advanced through the incision **105** and sutured to the annulus of the mitral valve **125**. The adjustment tool **135** is then manipulated, *e.g.*, rotated, depending upon the design of the adjustment means **130**, to cause the adjustment means to reduce the size of the implant body **115**, and hence the underlying mitral valve **125** to which it is sutured, to an approximate size. The myocardial incision **105** can now be closed, as shown in FIG. 5, leaving the adjustment tool extending through the incision for post-operative adjustment.

Once the patient has been taken "off pump" and normal flow of blood through the heart **110** has resumed, but before the chest incision has been closed, further adjustments to the size of the mitral valve **125** can be made by manipulating the adjustment tool **135**.

FIGS. 6–8 show an exemplary adjustment means **200** for adjusting the circumference of an annular implant such as the implant **100** previously described. The adjustment means **200** comprises a rack and pinion system in which a first cam **205** with geared teeth **210** and an engagement coupler **215** turns on a first axel **220**. In this

example, the first cam **205** engages a geared rack **225** on one or more surfaces of a first band **230**. The first band **230** passes between the first cam **205** and a second cam **235** that turns on a second axel **240** that is joined to a second band **245**. As shown in FIG. 8, the first and second axels **220**, **240** are maintained in suitable spaced-apart relation by means of a bracket **250** formed at the end of the second band **245**.

The adjustment means **200** is preferably set within a hollow annular implant **100** of the type previously described, though it is possible to use the adjustment means in a stand-alone configuration wherein the first and second bands **230**, **245** are opposing ends of the same continuous annular structure. In either event, to adjust the length of an implant comprising the adjustment means **200**, a tool such as a hex wrench engages the engagement coupler **215** on the first cam **205** and rotates the first cam in a counterclockwise direction as shown in FIG. 7, as indicated by the arrow **255**. Rotation of the first cam **205** causes the teeth **210** to drive the rack **225** to move the first band **230** toward the right, as indicated by the arrow **260** in FIG. 7. This movement of the first band tightens the circumference of the annular implant. If the physician inadvertently adjusts the implant too tight, reversing direction of the engagement coupler **215** will loosen the implant.

In various embodiments according to the present invention, the first and second bands **230**, **245** may be separate structures, or they may be opposing ends of the same continuous structure. In such an embodiment, when motion is imparted to the engagement coupler **215**, the first cam **205** is rotated, causing the geared teeth **210** to engage the geared rack **225**, and causing the first band **230** to move with respect to the second band **245** to adjust the circumference of an implant.

FIG. 9 shows a somewhat different configuration of an exemplary engagement means **300** according to the present invention, in which there is no engagement coupler, and a bracket **350** is provided on both sides of the cams to maintain the first cam **315** and the second cam **320** in close approximation. In one proposed embodiment, the bracket is designed with close tolerances so as to

press the first band **330** closely against the second band **345**, thereby to hold the bands in fixed relative position by friction. In another proposed embodiment, the brackets **350** are fabricated from an elastic material such that the cams **315**, **320** can be spread apart to insert the first band **330** between the cams, whereupon the cams are pulled back together with sufficient force to hold the bands **330**, **345** in fixed relative position by friction. In still another proposed embodiment involving an elastic mounting arrangement between the cams **315**, **320**, the lower edge of the first band **330** and the upper edge of the second band **345** have mating frictional or mechanical surfaces, whereby the cams **315**, **320** can be spread apart to permit relative movement between the bands or released to clamp the bands together in fixed relation.

FIG. 10 shows an exemplary attachment means **400** for an implant according to the present invention. The attachment means **400** could be used, for example, in place of the attachment means **25** of the implant **10**. The attachment means **400** takes the form of a grommet **410** comprising a wall **415** defining a lumen **420** and an attachment surface **425**. Such an attachment means would be used with the implant body extending through the lumen **420** and with fixation devices such as sutures or wires either tied over or affixed through the attachment surface **425**.

FIG. 11 shows another alternate embodiment of an attachment means **500** for an implant according to the present invention. The attachment means **500** could also be used, for example, in place of the attachment means **25** of the implant **10**. FIG. 11 shows an attachment means **500** in the form of a hollow tube or tube segment **510** comprising a wall **515** defining a lumen **520**, an outer surface **525**, and an attachment tab **530**. Such an attachment means would be used with the implant body extending through the lumen **520** and with fixation devices such as sutures or wires either tied or otherwise affixed over or through the attachment tab **530**. Such fixation devices might be placed through holes **535** provided in the attachment tab **530**. Alternately a solid attachment tab **530** might be provided, and the fixation devices might be passed through the solid tab.

Modifications of these attachment means may be used in conjunction with a sutureless attachment system.

FIGS. 12–18 show another embodiment of a percutaneous annuloplasty device according to the present invention, in which an implant/delivery system array **600** includes a housing sheath **605** (not seen in FIG. 12), an actuating catheter **610** coaxially slidably mounted within the housing sheath **605**, and a core catheter **615** coaxially slidably mounted within the actuating catheter **610**. The core catheter has a central lumen **616** (FIG. 13). The actuating catheter **610** and core catheter **615** may be round tubular structures, or as shown in FIG. 13, either or both of the actuating and core catheters may be provided with one or more keyed ridges **618**, **620** respectively to be received by one or more reciprocal slots **622**, **624** within the inner lumen of either the housing sheath **605** or the actuating catheter **610**, respectively. Such keyed ridges **618**, **620** would limit internal rotation of an inner element within an outer element, should such restriction be desirable to maintain control of the inner contents from inadvertent displacement due to undesired rotational motion during use.

The implant/delivery system array **600** includes a distal tip **625** at the forward end of the core catheter **615**. One or more radial implant support arms **630** have their distal ends **632** pivotably or bendably mounted to the core catheter **615** adjacent its distal tip **625**. The proximal ends **634** of the radial implant support arms **630** normally extend along the core catheter **615** but are capable of being displaced outward away from the core catheter.

One or more radial support struts **636** have their proximal ends **638** pivotably or bendably mounted to the distal end of the actuating catheter **610**. The distal end **640** of each radial support strut is **636** pivotably or bendably attached to a midpoint of a corresponding radial implant support arm **630**. As the actuating catheter **610** is advanced with respect to the core catheter **615**, the radial support struts **636** force the radial implant support arms **630** upward and outward in the fashion of an umbrella frame. Thus the actuating catheter **610**, core catheter **615**, radial support struts **636**, and radial support arms **630** in combination form a deployment umbrella **642**.

A prosthetic implant **645** is releasably attached to the proximal ends **634** of the radial implant support arms **630**. Around the periphery of the prosthetic implant **645** and extending proximally therefrom are a plurality of retention barbs **646**. In addition, one or more of the radial implant support arms **630** comprise touchdown sensors **648** whose proximal ends extend proximal to the implant **645**. Extending through the central lumen **616** (FIG. 13) of the core catheter **615** in the exemplary embodiment **600** and out lateral ports **650** (FIG. 12) spaced proximally from the distal tip **625** are one or more release elements **660**, which serve to release the implant **645** from the delivery system, and one or more adjustment elements **665** which serve to adjust the implant's deployed size and effect. Because the release elements **660** and adjustment elements **665** extend through the proximal end of the core catheter **615**, as seen in FIGS. 14–16, these elements can be directly or indirectly instrumented or manipulated by the physician. A delivery interface **670** (FIGS 12,16) is defined in this example by the interaction of the deployment umbrella **642,** the release elements **660**, and the implant **645**. In the disclosed embodiment, the release elements **660** may be a suture, fiber, or wire in a continuous loop that passes through laser-drilled bores in the implant **645** and in the radial implant support arms **630**, and then passes through the length of the core catheter **615**. In such an embodiment, the implant **645** may be released from the delivery system at a desired time by severing the release element **660** at its proximal end, outside the patient, and then withdrawing the free end of the release element **660** through the core catheter **610**.

FIGS. 14–16 show the operation of the implant/delivery system array **600**, in which an umbrella-like expansion of the prosthetic implant **645** is achieved by sliding movement of the housing sheath **605**, the actuating catheter **610**, and the core catheter **615**. Referring first to FIG. 14, the housing sheath **605** is extended to cover the forward ends of the actuating catheter **610** and core catheter **615** for intravascular insertion of the implant/delivery system array **600**. From this starting position, the housing sheath **605** is retracted in the direction indicated by the arrows **662**. In FIG. 15 the housing sheath

605 has been retracted to expose the forward end of the actuating catheter **610** and the collapsed deployment umbrella **642**. From this position the actuating catheter **610** is advanced in the direction indicated by the arrows **664**. This will cause the deployment umbrellas to expand in the directions indicated by the arrows **666**. FIG. 16 shows the expansion of the deployment umbrella **642** produced by distal motion of the actuating catheter **610** relative to the core catheter **615**. After the implant **645** has been positioned and adjusted to the proper size, the housing sheath **605** is advanced in the direction indicated by the arrows **668** to collapse and to cover the deployment umbrella **642** for withdrawal of the device from the patient.

FIGS. 17 and 18 are schematic views illustrating the radial implant support arms **630** and the radial support struts **636** of the implant/delivery system array **600**. In FIG. 17, a radial support strut **636** is pivotably attached at its proximal end **638** at a first pivotable joint **670** to the actuation catheter **610**. The radial support strut **636** is attached at its distal end **640** to a second pivotable joint **672** at an intermediate point of a corresponding radial implant support arm **630**. The radial implant support arm **630** is attached at its distal end **632** by a third pivotable joint **674** to the core catheter **620**. FIG. 17 shows the assembly in a closed state. When the actuation catheter **610** is advanced distally over the core catheter **615**, as shown by the arrows **676**, the radial support strut **636** and the radial implant support arm **630** are extended by the motion at the first pivotable joint **670**, the second pivotable joint **672**, and the third pivotable joint **674**, as shown by the arrow **678**. This motion has the effect of expanding the deployment umbrella and folded implant (not shown in FIGS. 17 and 18), allowing it to achieve its greatest radial dimension, prior to engagement and implantation as previously discussed with reference to FIGS. 12–16.

FIGS. 19 and 20 show further details of the touchdown sensors **648** shown previously in FIG. 12. The touchdown sensor **648** of FIGS. 19 and 20 includes a distal segment **680**, an intermediate segment **682**, and a proximal segment **684**. The distal segment **680** is

spring-mounted, so that it is capable of slidable, telescoping displacement over the intermediate segment **682** to achieve a seamless junction with the proximal segment **684** upon maximal displacement. When the touchdown sensor **648** is in its normal condition, the spring extends the proximal segment such that the sensor assumes the orientation shown in FIG. 19. When the implant **645** (FIG. 12) is seated against the periphery of an anatomical opening, the proximal segment **684** of the sensor **648** is compressed against the distal segment **680**, as shown in FIG. 20. The distal segment **680** and the proximal segment **684** are both constructed of, are sheathed by, or otherwise covered with a radio-opaque material. However, the intermediate segment **682** is not constructed or coated with such a radio-opaque material. Therefore, when the distal segment **680** is at rest, it is fully extended from the proximal segment **684**, and the gap represented by the exposed intermediate segment **682** is visible on radiographic examination. However, when the distal segment **680** is brought to maximum closeness with the proximal segment **684**, no such radio-opaque gap is radiographically visible, and the touchdown sensor is said to be "activated". This embodiment allows radiographic monitoring of the position of the touchdown sensor **648** with respect to the degree of extension of the distal catheter segment **680**. In the embodiment according to the present invention as shown, one or more touchdown detectors **648** are employed to ascertain that the delivery system for the prosthetic device is located in the proper position to deploy the implant into the mitral annulus. As this anatomic structure cannot be directly identified on fluoroscopy or standard radiographic procedures, such precise location could be otherwise difficult. At the same time, precise localization and engagement of the mitral annulus is critical for proper implant function and safety.

Touchdown detectors within the embodiments according to the present invention can have a multiplicity of forms, including the telescoping, spring-loaded, radio-opaque elements joined by a non-radio-opaque element as in the aforementioned examples. In embodiments employing magnetic resonance imaging, touchdown

detectors according to the present invention may utilize metallic segments interposed by nonmetallic segments in a similar telescoping, spring-loaded array. Other embodiments include a visually-evident system with telescoping, spring-loaded elements with color-coded or other visual features for procedures in which direct or endoscopic observation would be possible. Still other embodiments of touchdown detectors according to the present invention include touchdown detectors provided with microswitches at their tips, such that momentary contact of sufficient pressure completes an electrical circuit and signals the activation of the touchdown detector to the operator. Still other touchdown detectors according to the present invention are provided with fiberoptic pathways for Rahmen laser spectroscopy or other spectral analytical techniques which are capable of detecting unique tissue qualities of the tissue at the desired site for implantation. In addition, still other embodiments according to the present invention include touchdown detectors containing electrodes or other electronic sensors capable of detecting and signaling the operator when a desired electrophysiologic, impedance, or other measurable quality of the desired tissue is detected for proper implantation. Such electrophysiologic touchdown detectors may include electrical circuits that produce visual, auditory, or other signals to the operator that the detectors are activated and that the implant is in the proper position for attachment.

In yet other embodiments according to the present invention, other intracardiac or extracardiac imaging techniques including, but not limited to, intravascular ultrasound, nuclear magnetic resonance, virtual anatomic positioning systems, or other imaging techniques may be employed to confirm proper positioning of the implant, obviating the need for the touchdown sensors as previously described.

FIGS. 21–24 show an implant **700** according to one embodiment of the present invention. In this embodiment, the implant body **705** is bandlike and flexible. Through much of its length, the implant body **705** is provided with a series of retention barbs **710** which are oriented to facilitate placement, retention, and removal of the device. The implant body **705** is also provided with an adjustable

section **715**, which is provided in this example with a series of adjustment stops **720**. The adjustment stops **720** may be slots, holes, detents, dimples, ridges, teeth, raised elements, or other mechanical features to allow measured adjustment of the implant **700** in use. In the embodiment shown in FIGS. 21–24, the adjustment stops **720** are engaged by a geared connector **725**. FIG. 21 is an end view, showing the implant body **705** curved on itself, with the retention barbs **710** to the exterior, and with the adjustable section **715** passing through its engagement with the geared connector **725** and curving internally within the implant body **705** to form a closed, round structure. FIG. 23 shows details of an exemplary geared connector **725**, in which a housing **730** is connected to the implant body **705**. The housing **730** contains and supports a mechanical worm **740** with an attached first geared head **750** which mates with a second geared head **755**. The second geared head **755** is attached to an adjustment stem **760** which is machined to receive a screwdriver-like adjustment element. The various embodiments according to the present invention may require a number of forms of adjustment elements. In the present example, the adjustment element is provided as a finely coiled wire with a distal tip machined to be received by a receiving slot in the adjustment stem **760** (not shown). The relationship between the distal tip of the adjustment element and the adjustment stem **760** is mechanically similar to a screwdriver bit and screwhead, such that torsion imparted to the adjustment means by the operator will result in the turning of the adjustment stem **760** and second geared head **755** allows motion of the first geared head **750** and worm **740**, which creates motion of the adjustable implant section **715** as the worm engages with the series of adjustment tops **725**. Excess length of the adjustable section **715** passes though a band slot **735** (FIG. 23), thus allowing the band to move concentrically inside the closed implant body **705**. The adjustment element in this embodiment may be designed to remain in place after the deployment umbrella has been retracted and withdrawn. The connection between the adjustment element's distal tip and the adjustment stem **760** may be a simple

friction connection, a mechanical key/slot formation, or may be magnetically or electronically maintained.

As further shown in FIG. 21, the exemplary embodiment employs unidirectional retention barbs **710** which are attached to the outer perimeter of the implant body **705**. The retention barbs **710** are oriented in a consistent, tangential position with respect to the implant body **705** such that rotational motion of the implant body will either engage or release the retention barbs **710** upon contact with the desired tissue at the time of deployment. This positioning of the retention barbs **710** allows the operator to "screw in" the implant **700** by turning the implant **700** upon its axis, thus engaging the retention barbs **710** into the adjacent tissue. As shown in FIG. 24, the retention barbs **710** may each be further provided with a terminal hook **775** at the end which would allow for smooth passage through tissue when engaging the retention barbs **710** by rotating the implant **700**, without permitting the implant **700** to rotate in the opposite direction, because of the action of the terminal hooks **775** grasping the surrounding tissue (much like barbed fish hooks). The terminal hooks **775** thus ensure the seating of the implant **700** into the surrounding tissue.

FIGS. 25–27 illustrate another embodiment of an implant **800** as contemplated according to the present invention. The implant **800** includes a band **805** (FIG. 27), but the retention barbs of the previous example have been eliminated in favor of an outer fabric implant sheath **810**. The fabric sheath **810** can be sutured or otherwise affixed to the anatomic tissue in a desired location. The circumference of the implant body **800** is adjusted through a geared connector **825** similar to the geared connector of the bandlike implant array shown in FIG. 23. More specifically, adjustment stops **820** on the band are engaged by a mechanical worm **840** with an attached first geared head **850**. The first geared head **850** mates with a second geared head **855**. The second geared head **855** is attached to an adjustment stem **860** which is machined to receive a screwdriver-like adjustment element.

FIG. 28 illustrates an example of the method of use of an implant/delivery system array **600** for positioning an implant **645** in a patient with ischemic annular dilatation and mitral regurgitation.

Peripheral arterial access is obtained via conventional cutdown, arterial puncture, or other standard access techniques. After access to the arterial system is attained, guidewire placement is performed and intravascular access to the heart **900** is obtained using fluoroscopic, ultrasound, three-dimension ultrasound, magnetic resonance, or other real-time imaging techniques. The guidewire, deployment device, and implant are passed through the aortic valve in a retrograde fashion into the left ventricle **905** and then into the left atrium **910**. At this point, the operator retracts the housing sheath **605**, thus unsheathing the collapsed deployment umbrella **642** and implant **645**. The deployment umbrella **642** is then distended by the distal motion of the actuation catheter, causing the radial support arms and struts to fully distend. At this point, the touchdown detectors **648** are not in contact with any solid structures, and are fully extended with their radiolucent gaps visible on the imaging system. Once the deployment umbrella is distended, the entire assembly is pulled back against the area of the mitral valve **915**. At least two touchdown detectors **648** are employed in a preferred embodiment according to the present invention. When all touchdown detectors show the disappearance of their intermediate, non-opaque, intermediate segments and are thus activated, then the deployment umbrella must be in contact with the solid tissue in the region of the mitral annulus/atrial tissue, and further implant deployment and adjustment may proceed. However, if any one touchdown sensor is not activated, and a radiolucent gap persists, then the device is not properly positioned, and must be repositioned before further deployment. Thus, the touchdown sensor system may assist in the deployment and adjustment of prosthetic devices by the delivery system according to the present invention. Once properly positioned, the operator rotates the actuation catheter in a prescribed clockwise or counterclockwise manner to engage the retention barbs on the implant into the tissue in the region of the mitral annulus/atrial tissue. Should re-positioning be required, a reverse motion would disengage the retention barbs from the annular/atrial tissue, and repositioning may be performed, again using the touchdown detectors for proper placement. Once firmly seated, the adjustment element(s)

are operated to achieve the desired degree of annular reduction. Real-time trans esophageal echocardiography, intravascular echocardiography, intracardiac echocardiography, or other modalities for assessing mitral function may then be employed to assess the physiologic effect of the repair on mitral function, and additional adjustments may be performed. Once a desired result has been achieved, the release elements are activated to detach the implant from the deployment umbrella. The operator then retracts the actuation catheter and extends the housing sheath, collapsing the deployment umbrella and covering the components for a smooth and atraumatic withdrawal of the device from the heart and vascular system.

If desired, the adjustment elements may be left in position after the catheter components are withdrawn for further physiologic adjustment. In yet other embodiments according to the present invention, a catheter-based adjustment elements may subsequently be re-inserted though a percutaneous or other route. Such an adjustment element may be steerably operable by the operator, and may be provided with magnetic, electronic, electromagnetic, or laser-guided systems to allow docking of the adjustment element with the adjustable mechanism contained within the implant. In still other embodiments, the adjustment mechanism may be driven by implanted electromechanical motors or other systems, which may be remotely controlled by electronic flux or other remote transcutaneous or percutaneous methods.

In the case of pulmonic valve repair, initial catheter access is achieved through a peripheral or central vein. Access to the pulmonary valve is also achieved from below the valve once central venous access is achieved by traversing the right atrium, the tricuspid valve, the right ventricle, and subsequently reaching the pulmonic valve.

In yet other embodiments according to the present invention, catheter access to the left atrium can be achieved from cannulation of central or peripheral veins, thereby achieving access to the right atrium. Then a standard atrial trans-septal approach may be utilized to

access the left atrium by creation of an iatrogenic atrial septal defect (ASD). In such a situation, the mitral valve may be accessed from above the valve, as opposed to the retrograde access described in Example 1. The implant and a reversed deployment umbrella may be utilized with implant placement in the atrial aspect of the mitral annulus, with the same repair technique described previously. The iatrogenic ASD may then be closed using standard device methods. Access to the aortic valve may also be achieved from above the aortic valve via arterial access in a similar retrograde fashion.

Other embodiments of the adjustable implant and methods according to the present invention include gastrointestinal disorders such as gastro-esophageal reflux disease (GERD), a condition in which the gastro-esophageal (GE) junction lacks adequate sphincter tone to prevent the reflux of stomach contents into the esophagus, causing classic heartburn or acid reflux. This not only results in discomfort, but may cause trauma to the lower esophagus over time that may lead to the development of pre-cancerous lesions (Barrett's esophagus) or adenocarcinoma of the esophagus at the GE junction. Surgical repair of the GE junction has historically been achieved with the Nissen Fundoplication, an operative procedure with generally good results. However, the Nissen procedure requires general anesthesia and a hospital stay. Utilizing the devices and methods according to the present invention, an adjustable implant would obviate the need for a hospital stay and be performed in a clinic or gastroenterologist's office. Referring now to FIGS. 29 and 30, an umbrella deployment device **600** with implant **645** is passed under guidance of an endoscope **1000**, through the patient's mouth, esophagus **1005**, and into the stomach **1010**, where the deployment device **600** is opened with expansion of the implant **645** and touchdown detectors **648** with a color-coded or otherwise visible gap. The touchdown detectors are then engaged onto the stomach around the gastroesophageal junction **1015** under direct endoscopic control until all touchdown detectors **648** are visually activated. The implant is then attached to the stomach wall, **1020** the umbrella **642** is released and withdrawn, leaving behind the implant **645** and the

adjustment elements. The implant is then adjusted until the desired effect is achieved, i.e., minimal acid reflux either by patient symptoms, pH monitoring of the esophagus, imaging studies, or other diagnostic means. If the patient should suffer from gas bloat, a common complication of gastroesophageal junction repair in which the repair is too tight and the patient is unable to belch, the implant can be loosened until a more desirable effect is achieved.

In various embodiments anticipated by the present invention, the implant body may be straight, curved, circular, ovoid, polygonal, or some combination thereof. In various embodiments anticipated by the present invention the implant may be capable of providing a uniform or non-uniform adjustment of an orifice or lumen within the body. The implant body may further completely enclose the native recipient anatomic site, or it may be provided in an interrupted form that encloses only a portion of the native recipient anatomic site. In still other embodiments of the present invention, the implant body may be a solid structure, while in yet other embodiments the implant body may form a tubular or otherwise hollow structure. In one embodiment of the present invention, the body may further be a structure with an outer member, an inner member, and optional attachment members. In such an embodiment, the outer member of the implant body may serve as a covering for the implant, and is designed to facilitate and promote tissue ingrowth and biologic integration to the native recipient anatomic site. The outer member in such an embodiment may be fabricated of a biologically compatible material, such as Dacron, PTFE, malleable metals, other biologically compatible materials or a combination of such biologically compatible materials in a molded, woven, or non-woven configuration. The outer member in such an embodiment also serves to house the inner member. In this embodiment, the inner member provides an adjustment means that, when operated by an adjustment mechanism, is capable of altering the shape and/or size of the outer member in a defined manner.

In alternate embodiments according to the present invention, the adjustment means may be located external to or incorporated

within the outer member. In yet additional alternate embodiments contemplated by the present invention, the implant body may consist of an adjustment means without a separate outer member covering said adjustment means.

In various embodiments according to the present invention, the adjustment means may include a mechanism which may be threaded or non-threaded, and which may be engaged by the action of a screw or worm screw, a friction mechanism, a friction-detent mechanism, a toothed mechanism, a ratchet mechanism, a rack and pinion mechanism, or such other devices to permit discreet adjustment and retention of desired size a desired position, once the proper size is determined.

In yet other embodiments according to the present invention, the adjustment means may comprise a snare or purse string-like mechanism in which a suture, a band, a wire or other fiber structure, braided or non-braided, monofilament or multifilament, is capable of affecting the anatomic and/or physiologic effects of the implant device on a native anatomic recipient site upon varying tension or motion imparted to said wire or fiber structure by a surgeon or other operator. Such an adjustment means may be provided as a circular or non-circular structure in various embodiments. Changes in tension or motion may change the size and/or shape of the implant.

In various embodiments according to the present invention, the adjustment means may be a metallic, plastic, synthetic, natural, biologic, or any other biologically-compatible material, or combination thereof. Such adjustment means may further be fabricated by extrusion or other molding techniques, machined, or woven. Furthermore, in various embodiments of the present invention, the adjustment means may be smooth or may include slots, beads, ridges, or any other smooth or textured surface.

In various embodiments of the present invention, the implant body may be provided with one or more attachment members such as grommets or openings or other attachment members to facilitate attachment of the implant to the native recipient site. In alternate embodiments, the implant body may attach to or incorporate a

mechanical tissue interface system that allows a sutureless mechanical means of securing the implant at the native recipient site. In still other alternate embodiments, sutures or other attachment means may be secured around or through the implant body to affix the implant body to the native recipient site. In yet other embodiments of the present invention, mechanical means of securing the implant body to the native recipient site may be augmented or replaced by use of fibrin or other biologically-compatible tissue glues or similar adhesives.

In additional various embodiments according to the present invention, the adjustable implant may be employed to adjustably enlarge or maintain the circumference or other dimensions of an orifice, ostium, lumen, or anastomosis in which a disease process tends to narrow or constrict such circumference or other dimensions.

In various embodiments according to the present invention, an adjustment mechanism may be provided to interact with the adjustment means to achieve the desired alteration in the size and/or position of the adjustment means. Such an adjustment mechanism may include one or more screws, worm-screw arrays rollers, gears, frictional stops, a friction-detent system, ratchets, rack and pinion arrays, micro-electromechanical systems, other mechanical or electromechanical devices or some combination thereof.

In some embodiments as contemplated by the present invention, an adjustment tool may be removably or permanently attached to the adjustment mechanism and disposed to impart motion to the adjustment mechanism and, in turn, to the adjustment means to increase or decrease the anatomic effect of the implant on the native recipient site.

In alternate embodiments according to the present invention, micromotor arrays with one or more micro-electromechanical motor systems with related electronic control circuitry may be provided as an adjustment means, and may be activated by remote control through signals convey by electromagnetic radiation or by direct circuitry though electronic conduit leads which may be either permanently or removably attached to said micromotor arrays.

In still other various embodiments according to the present invention, the adjustment mechanism may be provided with a locking mechanism disposed to maintain the position of the adjustment means in a selected position upon achievement of the optimally desired anatomic and/or physiologic effect upon the native recipient site and the bodily organ to which it belongs. In other embodiments, no special locking mechanism may be necessary due to the nature of the adjustment means employed.

In yet other alternate embodiments according to the present invention, the adjustment means and/or the outer member structure may be a pliable synthetic material capable of rigidification upon exposure to electromagnetic radiation of selected wavelength, such as ultraviolet light. In such embodiments, exposure to the desired electromagnetic radiation may be achieved by external delivery of such radiation to the implant by the surgeon, or by internal delivery of such radiation within an outer implant member using fiberoptic carriers placed within said outer member and connected to an appropriate external radiation source. Such fiberoptic carriers may be disposed for their removal in whole or in part from the outer implant member after suitable radiation exposure and hardening of said adjustment means.

The present invention also provides methods of using an adjustable implant device to selectively alter the anatomic structure and/or physiologic effects of tissues forming a passageway for blood, other bodily fluids, nutrient fluids, semi-solids, or solids, or wastes within a mammalian body. Various embodiments for such uses of adjustable implants include, but are not limited to, open surgical placement of said adjustable implants at the native recipient site through an open surgical incision, percutaneous or intravascular placement of said implants under visual control employing fluoroscopic, ultrasound, magnetic resonance imaging, or other imaging technologies, placement of said implants through tissue structural walls, such as the coronary sinus or esophageal walls, or methods employing some combination of the above techniques. In various embodiments as contemplated by the present invention,

adjustable implants may be placed and affixed in position in a native recipient anatomic site by trans-atrial, trans-ventricular, trans-arterial, trans-venous (i.e., via the pulmonary veins) or other routes during beating or non-beating cardiac surgical procedures or endoscopically or percutaneously in gastrointestinal surgery.

Furthermore, alternate methods for use of an adjustable implant device may provide for the periodic, post-implantation adjustment of the size of the anatomic structure receiving said implant device as needed to accommodate growth of the native recipient site in a juvenile patient or other changes in the physiologic needs of the recipient patient.

Adjustment of the adjustable implants and the methods for their use as disclosed herein contemplates the use by the surgeon or operator of diagnostic tools to provide an assessment of the nature of adjustment needed to achieve a desired effect. Such diagnostic tools include, but are not limited to, transesophageal echocardiography, echocardiography, diagnostic ultrasound, intravascular ultrasound, virtual anatomic positioning systems integrated with magnetic resonance, computerized tomographic, or other imaging technologies, endoscopy, mediastinoscopy, laparoscopy, thoracoscopy, radiography, fluoroscopy, magnetic resonance imaging, computerized tomographic imaging, intravascular flow sensors, thermal sensors or imaging, remote chemical or spectral analysis, or other imaging or quantitative or qualitative analytic systems.

In one aspect, the implant/delivery system of the present invention comprises a collapsible, compressible, or distensible prosthetic implant and a delivery interface for such a prosthetic implant that is capable of delivering the prosthetic implant to a desired anatomic recipient site in a collapsed, compressed, or non-distended state, and then allowing controlled expansion or distension and physical attachment of such a prosthetic implant by a user at the desired anatomic recipient site. Such a system permits the delivery system and prosthetic implant to be introduced percutaneously through a trocar, sheath, via Seldinger technique, needle, or endoscopically through a natural bodily orifice, body cavity, or region

and maneuvered by the surgeon or operator to the desired anatomic recipient site, where the delivery system and prosthetic implant may be operably expanded for deployment. When desirable, the implant/delivery system according to the present invention is also capable of allowing the user to further adjust the size or shape of the prosthetic implant once it has been attached to the desired anatomic recipient site. The delivery system according to the present invention is then capable of detaching from its interface with the prosthetic implant and being removed from the anatomic site by the operator. The delivery system and prosthetic implant may be provided in a shape and size determined by the anatomic needs of an intended native recipient anatomic site within a mammalian patient. Such a native recipient anatomic site may be a heart valve, the esophagus near the gastro-esophageal junction, the anus, or other anatomic sites within a mammalian body that are creating dysfunction that might be relieved by an implant capable of changing the size and shape of that site and maintaining a desired size and shape after surgery.

In various embodiments contemplated by the present invention, the delivery system may be a catheter, wire, filament, rod, tube, endoscope, or other mechanism capable of reaching the desired recipient anatomic site through an incision, puncture, trocar, or through an anatomic passageway such as a vessel, orifice, or organ lumen, or trans-abdominally or trans-thoracically. In various embodiments according to the present invention, the delivery system may be steerable by the operator. The delivery system may further have a delivery interface that would retain and convey a prosthetic implant to the desired recipient anatomic site. Such a delivery interface may be operably capable of distending, reshaping, or allowing the independent distension or expansion of such a prosthetic implant at the desired recipient anatomic site. Furthermore, such a delivery interface may provide an operable means to adjust the distended or expanded size, shape, or physiologic effect of the prosthetic implant once said implant has been attached *in situ* at the desired recipient anatomic site. In various embodiments according to the present invention, such adjustment may be carried out during the

procedure in which the implant is placed, or at a subsequent time. Depending upon the specific anatomic needs of a specific application, the delivery interface and the associated prosthetic implant may be straight, curved, circular, helical, tubular, ovoid, polygonal, or some combination thereof. In still other embodiments of the present invention, the prosthetic implant may be a solid structure, while in yet other embodiments the prosthetic implant may form a tubular, composite, or otherwise hollow structure. In one embodiment of the present invention, the prosthetic implant may further be a structure with an outer member, an inner member, and optional attachment members. In such an embodiment, the outer member of the prosthetic implant may serve as a covering for the implant, and is designed to facilitate and promote tissue ingrowth and biologic integration to the native recipient anatomic site. The outer member in such an embodiment may be fabricated of a biologically compatible material, such as Dacron, PTFE, malleable metals, other biologically compatible materials or a combination of such biologically compatible materials in a molded, woven, or non-woven configuration. The outer member in such an embodiment also serves to house the inner member. In this embodiment, the inner member provides an adjustment means that, when operated by an adjustment mechanism, is capable of altering the shape and/or size of the outer member in a defined manner.

In some embodiments according to the present invention, at least some portions of the adjustable inner or outer member may be elastic to provide an element of variable, artificial muscle tone to a valve, sphincter, orifice, or lumen in settings where such variability would be functionally valuable, such as in the treatment of rectal incontinence or vaginal prolapse.

In various embodiments according to the present invention, the delivery interface would have an attachment means to retain and convey the prosthetic implant en route to the native anatomic recipient site and during any *in situ* adjustment of the prosthetic implant once it has been placed by the operator. Such an attachment means would be operably reversible to allow detachment of the

prosthetic implant from the delivery interface once desired placement and adjustment of the prosthetic implant has been accomplished.

Finally, it will be understood that the preferred embodiment has been disclosed by way of example, and that other modifications may occur to those skilled in the art without departing from the scope and spirit of the appended claims.